IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Palmetto Pharmaceuticals LLC, Plaintiff, v. AstraZeneca Pharmaceuticals LP, Defendant.	Civil Action No. 2:11-807-SB **ORDER**

Palmetto Pharmaceuticals LLC ("the Plaintiff" or "Palmetto") filed this patent infringement action against AstraZeneca Pharmaceuticals LP ("the Defendant" or "AstraZeneca") on April 5, 2011. On May 16, 2011, the Plaintiff filed an amended complaint alleging direct, induced, contributory, and willful infringement of United States Patent No. 6,465,516 ("the '516 patent") pursuant to 35 U.S.C. § 271(a)-(c).

On. June 15, 2011, the Defendant filed a motion to dismiss, or in the alternative, for summary judgment. Then, on November 15, 2011, pursuant to 28 U.S.C. § 636 and Local Civil Rule 73.02(C)(7), D.S.C., the Court referred this matter to United States Magistrate Judge Jacquelyn D. Austin for pre-trial management. On January 4, 2012, Magistrate Judge Austin issued a report and recommendation ("R&R") outlining the issues and recommending that the Court grant the Defendant's motion as to the Plaintiff's claims of direct infringement under 28 U.S.C. § 271(a) and contributory infringement under 35 U.S.C. § 271(c), but that the Court deny the Defendant's motion as to the Plaintiff's claims of induced infringement under 35 U.S.C. § 271(b) and willful infringement. When neither party filed objections to the R&R, the Court issued an order on February 14, 2012, adopting the Magistrate Judge's recommendations.

The parties pursued limited discovery on the issues of infringement and inducement. On July 13, 2012, the Defendant filed a motion for summary judgment arguing that it did not induce doctors to infringe the '516 patent under 35 U.S.C. § 271(b). The Plaintiff responded to the Defendant's motion and proffered evidence, including the expert testimony of Drs. John Hallett, Uri Elkayam, and Jerry Back. On August 21, 2012, the Defendant filed a motion to strike allegedly objectionable evidence relied upon by the Plaintiff, as well as a motion to exclude the Plaintiff's experts pursuant to the Federal Rules of Evidence and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). The Magistrate Judge held a hearing on these three motions on November 29, 2012. On February 26, 2013, Magistrate Judge Austin filed an R&R recommending that the Court deny the Defendant's motion for summary judgment. At the same time, Magistrate Judge Austin filed an order finding the Defendant's evidentiary motions moot.

On March 18, 2013, the Defendant filed objections to the R&R. The Plaintiff filed a response, and the Defendant filed a reply. In its objections, the Defendant asserts that the Magistrate Judge erred by failing to perform the gatekeeper function prior to deciding the summary judgment motion and that no genuine issue of material fact exists.

On May 8, 2013, the Defendant filed a motion for a status conference. As a result, the Court scheduled a hearing for July 23, 2013, at which hearing the Court decided that it was not fair to rule on the Defendant's summary judgment motion without first deciding the Defendant's Daubert motion. Therefore, on September 11, 2013, the Court held a hearing on the Daubert motion, following which the Court asked the parties to submit proposed findings of fact and conclusions of law along with any supplemental briefs the parties wished to file. The parties filed supplemental briefs and proposed findings and

conclusions on November 15, 2013.

After a review of the record, including the R&R, the Defendant's objections, the hearing transcripts, the parties' various briefs, and their proposed findings and conclusions, the Court issues this order denying the Defendant's Daubert motion and the Defendant's motion for summary judgment.

BACKGROUND

The Plaintiff is the assignee and lawful owner of the '516 patent, which issued on October 15, 2002, as amended by Reexamination Certificate No. 6,465,516 C1, which issued on April 5, 2011. The '516 patent claims a method of treating nonhyperlipidemic subjects, i.e., people who do not have hyperlipidemia, who would benefit from increased nitric oxide ("NO") production. Claim 1 of the '516 patent, as amended, claims:

> 1. A method for treating a nonhyperlipidemic subject who would benefit from increased Nitric Oxide production in a tissue comprising:
>
> administering to the nonhyperlipidemic subject in need of such treatment a Hmg-CoA reductase inhibitor in an amount effective to increase Nitric Oxide production in said tissue of the subject.

(Entry 27-2 at 16.)

In 2003, the Defendant began marketing a statin, rosuvastatin calcium, under the trademark CRESTOR®. Also in 2003, the United States Food and Drug Administration ("FDA") approved CRESTOR® for three uses or indications, including the treatment of people with hyperlipidemia and, within that group, people with elevated cholesterol levels. In addition, in 2003, the Defendant began enrolling patients in a clinical trial–the JUPITER trial–to evaluate the efficacy of CRESTOR® in reducing cardiovascular events for people who did not have hyperlipidemia but who did have cardiovascular risk factors. On February

8, 2010, the FDA approved the use of CRESTOR® for indications resulting from the JUPITER trial, including Indication 1.6, which is at issue in this case. Indication 1.6 can be found in the package insert accompanying CRESTOR®, and it provides the following:

> In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥50 years old in men and ≥60 years old in women, [high sensitivity C-reactive protein ("hsCRP")] ≥2mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CRESTOR is indicated to:
> - reduce the risk of stroke
> - reduce the risk of myocardial infarction
> - reduce the risk of arterial revascularization procedures

(Entry 41-4 at 5.)

In this action, the Plaintiff claims that the Defendant is infringing upon its patent because treating a nonhyperlipidemic individual with an elevated hsCRP by administering CRESTOR® is the same thing as treating a subject who would benefit from increased NO production by administering an Hmg-CoA reductase inhibitor in an amount effective to increase NO production. The Defendant, in its motion for summary judgment, contends that no reasonable juror could find a relationship between CRP levels and NO production in humans such that measuring a patient's CRP level is the same as measuring a patient's NO production. The Defendant also argues that the Plaintiff has no admissible evidence to show that Indication 1.6 or related promotional materials instruct or encourage infringement. Further, the Defendant contends that the record evidence does not show that it has promoted CRESTOR® to increase NO levels in humans.

Next, with regard to the Plaintiff's proposed expert testimony, the Defendant contends: that Drs. Hallett and Elkayam are not qualified to offer an opinion on the alleged

association between CRP and NO; that Drs. Hallett and Elkayam have no reliable proof of an association between CRP and NO in humans; that the experts failed to consider contradictory data; that the opinions of Drs. Hallett and Elkayam are unscientific and litigation-driven; and that Dr. Back is nothing more than a mouthpiece for Dr. Elkayam.

ANALYSIS

Rule 702 of the Federal Rules of Evidence "imposes a special obligation upon a trial judge to ensure that any and all scientific testimony is not only relevant, but reliable." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (internal quotation marks omitted). In addition to ensuring the relevancy and reliability of expert testimony, the gatekeeping role of the Court ensures "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id. at 152. In that regard, Rule 702 provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed.R.Evid. 702. In serving as the gatekeeper for expert testimony, the Court must address two questions: first, whether the expert's testimony is based on "scientific knowledge"; and second, whether the testimony "will assist the trier of fact to understand

or determine a fact in issue." Daubert, 509 U.S. at 592. The first question is answered by assessing "whether the reasoning or methodology underlying the testimony is scientifically valid." Id. at 592-93. In Daubert, the Supreme Court identified five nondispositive factors for evaluating the reliability of proposed expert testimony: (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. See United States v. Crisp, 324 F.3d 261, 265-66 (4th Cir.2003) (quoting Daubert, 509 U.S. at 593-94). The Daubert test is flexible, however; "[r]ather than providing a definitive or exhaustive list, Daubert merely illustrates the types of factors that will bear on the inquiry." Id. at 266. As the Court of Appeals for the Fourth Circuit has noted: "In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful; the particular factors will depend upon the unique circumstances of the expert testimony involved." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999).

The second inquiry "goes primarily to relevance." Daubert, 509 U.S. at 591. Relevance is determined by ascertaining whether the testimony is sufficiently tied to the facts of the case such that it will aid the jury in resolving a factual dispute. Id. at 593.

"A review of the case law after Daubert shows that the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702, Advisory Committee's Note to 2000 Amendments. "Daubert did not work a 'seachange over federal evidence law,' and

'the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system.' " Id. (quoting United States v. 14.38 Acres of Land Situated in Leflore Cnty., 80 F.3d 1074, 1078 (5th Cir.1996)).

Here, after much consideration, the Court finds that Drs. Hallett, Elkayam, and Back are sufficiently qualified by their knowledge, skill, experience, training, and education, and that they may give relevant and reliable testimony on the relationship between CRP and NO. In so finding, the Court has considered both the bases for the doctors' opinions as well as the potential relevance of their opinions to the issues presented in this case.

Dr. Hallett, a vascular surgeon and the medical director of the Roper St. Francis Heart and Vascular Center in Charleston, South Carolina, opines that (1) NO plays a critical role in maintaining cardiovascular health, and NO deficiency is implicated in all cardiovascular disease; (2) insufficient NO production and/or bioavailability will lead to a decline in cardiovascular health and may lead to cardiovascular conditions such as hypertension and an increased risk of cardiovascular events such as stroke; (3) elevated CRP levels in a subject correspond to decreased NO production and bioavailability, and they indicate the subject is at an increased risk for cardiovascular conditions and events; and (4) statins including CRESTOR® increase NO production and bioavailability and thus will provide a medical benefit to patients who have decreased NO production by decreasing the risk of cardiovascular conditions and events. Dr. Hallett bases these opinions on his full range of education, training, and experience as well as his review of peer-reviewed scientific publications. The Court finds his opinions sufficiently reliable and relevant under Rule 702 of the Federal Rules of Evidence and Daubert.

Likewise, the Court finds the opinion of Dr. Elkayam sufficiently reliable to withstand

review under Rule 702 and Daubert. Dr. Elkayam, a cardiologist, researcher, and treating physician with more than 30 years of experience, offers the following opinions: (1) that the role of NO in cardiovascular health is well-known in the medical community; (2) that decreased NO production or bioavailability is associated with cardiovascular disease; (3) that administering a statin to a person meeting the criteria of Indication 1.6 is the same as administering a statin to a person in need of increased NO; and (4) that administering CRESTOR® to a person meeting the Indication 1.6 criteria will increase NO production and provide a medical benefit. Here again, he bases these opinions on his years of education, training, and experience and his review of peer-reviewed scientific publications.

Finally, the Court finds that Dr. Back, who is the medical director and clinician at Advanced Centers for Hypertension, Diabetes & Cholesterol Disorders in Ladson, South Carolina, may offer relevant and reliable testimony as to the generally accepted practices of physicians prescribing CRESTOR® insofar as these opinions are based on his personal experience and training and his review of peer-reviewed scientific publications as well as his consultation with others in the field. The Court notes, however, that although Dr. Back may offer his opinions related to the clinical practice of medicine, he may not simply reiterate the expert opinions of Drs. Hallett or Elkayam.

Based on the foregoing, the Court denies the Defendant's Daubert motion at this time. In denying the motion, the Court notes that its role is not to evaluate the correctness of the facts underlying these experts' opinions; rather, its job is to evaluate the legal sufficiency of the opinions. In other words, in acting as gatekeeper, the Court does not function as fact finder. To the extent the Defendant finds fault with the qualifications and opinions of the Plaintiff's experts, questions about the experts' credentials and the bases

for their opinions are ideal fodder for cross-examination. As the Supreme Court noted in Daubert, the "conventional devices" of "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 596.

Having denied the Defendant's Daubert motion, the next question for the Court is whether the Defendant is entitled to summary judgment. As previously mentioned, the Magistrate Judge recommended denying the Defendant's motion for summary judgment without specifically ruling on the Defendant's Daubert motion. The Defendants objected (and the Court agreed with the Defendants) that it was not appropriate to rule on the summary judgment motion without first ruling on the Daubert motion. Now, having determined that the Plaintiff's experts may offer testimony on the scientific relationship between CRP and NO, the Court wholly agrees with the Magistrate Judge that genuine issues of material fact exist both as to whether a doctor prescribing CRESTOR® pursuant to Indication 1.6 infringes on claim 1 of the '516 patent, and as to whether the Defendant knew that its actions would induce infringement of the '516 patent and intended to induce such infringement. Therefore, for the reasons set forth by the Magistrate Judge in the R&R, the Court denies the Defendant's motion for summary judgment.

More recently, the Defendant also filed a motion to strike the supplemental report of Dr. Hallett, arguing that it was untimely under the scheduling order; that it is improper supplementation under Rule 26(e)(2); and that it is not substantially justified or harmless. The Plaintiff opposes the Defendant's motion and asserts that the report is a timely and a proper supplemental report. After consideration of the parties' arguments (and the record as a whole), the Court declines to strike the supplemental report of Dr. Hallett,

finding that its inclusion at this time is both substantially justified and harmless. Accordingly, the Court denies the Defendant's motion to strike the supplemental report of Dr. Hallett.

CONCLUSION

Based on the foregoing, the Court denies the Defendant's motion to strike the Plaintiff's experts (Entry 203). Next, having denied the Defendant's Daubert motion, the Court finds, for the reasons stated herein and for the reasons set forth by the Magistrate Judge in the R&R (Entry 265) that genuine issues of material fact exist as to whether the Defendant directly infringed the '516 patent and as to whether the Defendant acted with the requisite knowledge or specific intent to infringe. Therefore, the Court denies the Defendant's motion for summary judgment (Entry 134). The Court also denies the Defendant's motion to strike the supplemental report of Dr. Hallett (Entry 320). The parties consent to the Plaintiff's motion to seal its supplemental Daubert brief; accordingly, the Court grants the motion (Entry 322). Finally, the Court requests that the parties confer and submit a proposed amended scheduling order (or orders if the parties cannot agree) within fourteen days of the date of this order.

IT IS SO ORDERED.

Sol Blatt, Jr.
Senior United States District Judge

April 2, 2014
Charleston, South Carolina

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